



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/688,365

10/17/2003

Andrew Thomas Forsberg

47563.0013

2302

57600

7590

08/07/2008

HOLLAND & HART LLP

60 E. South Temple, Suite 2000

P.O. Box 11583

Salt Lake City, UT 84110

EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

08/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/688,365	Applicant(s) FORSBERG, ANDREW THOMAS	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Prosecution on the merits of this application is reopened, all previously indicated allowable claims are withdrawn. Claims 1-62 are pending. Claims 1, 21, 33, 38, 43, 50, 55, and 60 are independent.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claims 33-37, the word "means" is preceded by the word(s) "locking" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3773

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 21, 33-35, 43-46, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681).

In regard to Claims 1, 21, 33-36, 43-46, 60, and 61, Evans et al discloses a vascular closure assembly, comprising: a collagen (**22**); a suture (**24A, 24B, and 24C**) extending through the collagen; a housing (**46**); a tamping tube (**28**); a straight channel (**48**); a suture locking mechanism (movement of inner surface of 48, Col. 8, lines 40-57) residing in the housing; wherein the suture locking mechanism comprises a non-locked position (the non-locking position occurs when 48 is not collapsed, Col. 8, lines 40-57) and a locked position (the non-locking position occurs when 48 is collapsed, Col. 8, lines 40-57); wherein the suture would engage the suture locking mechanism; wherein the locking mechanism has at least one locking element (inner surface of 48), wherein the at least one locking element has a first orientation (the first orientation occurs when 48 is not collapsed, Col. 8, lines 40-57) and a second orientation (the second orientation occurs when 48 is collapsed, Col. 8, lines 40-57); the first orientation providing the suture with a relatively non-tortuous path; the second orientation providing the suture

relative tortuous path (Fig. 14 and Col. 8, lines 40-57); the tortuous suture pathway is formed by narrowing of the channel (Fig. 14 and Col. 8, lines 40-57).

Evans et al does not appear to disclose an anchor and the channel comprises at least one curved portion. However, Nash et al teaches a vascular closure assembly, comprising: an anchor (**32**). Evans et al and Nash et al are analogous art because they are from the same field of endeavor. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Evans et al and Nash et al before him or her, to modify the vascular closure assembly of Evans et al to include an anchor as taught by Nash. The suggestion/motivation for doing so would have been to maintain the vascular closure assembly to be secured to the vascular aperture (Nash et al, Fig. 3). Applicant should be noted that the curved portion of the channel is only a design choice and within the skill of one of ordinary skill in the art.

8. Claims 2-8, 10-18, 20, 22-31, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681) as applied to 1, 21, and 43-46 above, and further in view of Goble et al (US Pat. No.: 5,702,397).

In regards to Claims 2-8, 10-18, 20, 22-31, 47, and 48, Evans et al in view of Nash et al discloses all the limitations of the claims but fails to disclose the claimed structure of the suture locking assembly or the claimed suture locking mechanism.

However, Goble et al discloses: a suture locking mechanism, wherein a suture locking mechanism changes from the non-locking position to the locking position by rotational movement (Fig. 18); wherein the suture locking mechanism comprises: a

Art Unit: 3773

plurality of locking posts (**107b**); wherein a first surface area of the plurality of locking posts is adapted to be in contact with a suture providing a first amount of frictional resistance to movement of the suture in the non-locking position; and a second surface area of plurality of locking posts is adapted to be in contact with the suture providing a second amount of frictional resistance to movement of the suture; wherein the first surface area is less than the second surface area (Fig. 18, when 107 is moved to the right, less surface area of 107 would contact the suture); wherein the suture locking mechanism rotates from the non-lock position to the locked position (Fig. 18); at least one of the plurality of locking posts comprises a grooved surface (107b has a grooved surface); wherein the suture locking post comprise of elliptical shape (the grooved surface is elliptical shape); wherein the suture locking mechanism comprises at least one channel (**103**) through the housing; wherein the at least one channel is arranged such that it provides a substantially non-tortuous suture path when the suture locking mechanism is in the non-locking position; and the at least one channel is arranged such that it provides a substantially tortuous suture path when the suture locking mechanism is in the locked position (Fig. 18); wherein the non-tortuous path is substantially parallel to the suture and the tortuous path has at least a portion that is substantially non-parallel to the suture (Fig. 18); wherein the channel is substantially straight (Fig. 18); wherein the channel has at least one bend (the channel 103 has a curved wall, Fig. 18); the channel comprises: a wide end; and a narrow end; the narrow end comprises a ribbed surface (**112**); and the suture locking mechanism comprises: at least one pair of

mating surfaces (**107b and 112**), wherein when in the non-locked position the at least one pair of mating surfaces are separated.

Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al to include the suture locking mechanism as taught by Goble et al. It would have been obvious to have applied any of the various suture locking mechanisms or device as taught by Goble et al instead of that disclosed by Evans, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's. In addition, it would have been obvious to modify the narrow end to be coated with an adhesive to increase frictional resistance since it is an obvious alternative of a grooved surface which would also increase the frictional resistance.

9. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681) Goble et al (US Pat. No.: 5,702,397), as applied to claims 1 and 2 above, and further in view of Lam et al (US Pub. No.: 2004/0147958).

In regard to Claims 6 and 9, Evans et al in view of Nash et al and Goble et al discloses all the limitations of the claims but fails to disclose the claimed suture locking mechanism. However, Lam et al teaches a suture locking mechanism rotates from non-locked position to the locked position (Figs. 9A-9C). Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al to include the suture locking mechanism as taught by Lam et al. It would have been obvious to have applied any of the various suture locking

mechanisms or device as taught by Goble et al instead of that disclosed by Evans, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's. In addition, the cause of the rotational movement is only a design choice as long as the locking mechanism properly locks the suture by rotating the non-locked position to the locked position.

10. Claims 38-41 and 55 rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681) and Goble et al (US Pat. No.: 5,702,397).

In regard to Claims 38-41 and 55, Evans et al discloses a vascular closure assembly, comprising: a collagen (**22**); a suture (**24A, 24B, and 24C**) extending through the collagen; a housing (**46**); a straight channel (**48**); a suture locking mechanism (movement of inner surface of 48, Col. 8, lines 40-57) residing in the housing; wherein the suture locking mechanism comprises a non-locked position (the non-locking position occurs when 48 is not collapsed, Col. 8, lines 40-57) and a locked position (the non-locking position occurs when 48 is collapsed, Col. 8, lines 40-57); wherein the suture would engage the suture locking mechanism; wherein the locking mechanism has at least one locking element (inner surface of 48), wherein the at least one locking element has a first orientation (the first orientation occurs when 48 is not collapsed, Col. 8, lines 40-57) and a second orientation (the second orientation occurs when 48 is collapsed, Col. 8, lines 40-57); the first orientation providing the suture with a relatively non-tortuous path; the second orientation providing the suture relative tortuous path (Fig. 14

and Col. 8, lines 40-57); the tortuous suture pathway is formed by narrowing of the channel (Fig. 14 and Col. 8, lines 40-57).

Evans et al does not appear to disclose an anchor and the claimed structure of the suture locking assembly or the claimed suture locking mechanism. However, Nash et al teaches a vascular closure assembly, comprising: an anchor (**32**). Evans et al and Nash et al are analogous art because they are from the same field of endeavor. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Evans et al and Nash et al before him or her, to modify the vascular closure assembly of Evans et al to include an anchor as taught by Nash. The suggestion/motivation for doing so would have been to maintain the vascular closure assembly to be secured to the vascular aperture (Nash et al, Fig. 3).

In addition, Goble et al discloses: a suture locking mechanism, wherein a suture locking mechanism changes from the non-locking position to the locking position by rotational movement (Fig. 18); wherein the suture locking mechanism comprises: a plurality of locking posts (**107b**); wherein a first surface area of the plurality of locking posts is adapted to be in contact with a suture providing a first amount of frictional resistance to movement of the suture in the non-locking position; and a second surface area of plurality of locking posts is adapted to be in contact with the suture providing a second amount of frictional resistance to movement of the suture; wherein the first surface area is less than the second surface area (Fig. 18, when 107 is moved to the right, less surface area of 107 would contact the suture); wherein the suture locking mechanism rotates from the non-lock position to the locked position (Fig. 18); at least

one of the plurality of locking posts comprises a grooved surface (107b has a grooved surface); wherein the suture locking post comprise of elliptical shape (the grooved surface is elliptical shape); wherein the suture locking mechanism comprises at least one channel (**103**) through the housing; wherein the at least one channel is arranged such that it provides a substantially non-tortuous suture path when the suture locking mechanism is in the non-locking position; and the at least one channel is arranged such that it provides a substantially tortuous suture path when the suture locking mechanism is in the locked position (Fig. 18); wherein the non-tortuous path is substantially parallel to the suture and the tortuous path has at least a portion that is substantially non-parallel to the suture (Fig. 18); wherein the channel is substantially straight (Fig. 18); wherein the channel has at least one bend (the channel 103 has a curved wall, Fig. 18); the channel comprises: a wide end; and a narrow end; the narrow end comprises a ribbed surface (**112**); and the suture locking mechanism comprises: at least one pair of mating surfaces (**107b and 112**), wherein when in the non-locked position the at least one pair of mating surfaces are separated.

Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al in view of Nash et al to include the suture locking mechanism as taught by Goble et al. It would have been obvious to have applied any of the various suture locking mechanisms or device as taught by Goble et al instead of that disclosed by Evans in view of Nash et al, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's in view of Nash et al.

11. Claims 19, 32, 37, 42, 49-52, 54, 56-59, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681), Goble et al (US Pat. No.: 5,702,397) and further in view of Schwartz et al (US Pat. No.: 6,293,961).

In regard to Claims 19, 32, 37, 42, 49-52, 54, 56-59, and 62, Evans et al in view of Nash et al and Goble et al discloses all the limitations of the claims except claimed structures of the housing which serves as part of locking mechanism.

However, Schwartz et al teaches a vascular closure assembly, comprising: a housing (**60**), the housing comprises at least a first hole (the conical hole of 60, Fig. 7) corresponding to the first position and at least a second hole (the cylindrical hole of 60) corresponding to the second position; and a locking device or inner housing assembly (**20**), the locking device or inner housing assembly comprises at least a tab (**34**); wherein the housing comprises sidewalls (Fig. 7), such that sidewalls provide angle inwards from at least the first hole to at least the second hole; wherein the inward slope of the sidewalls provides a compressive force on the locking device tending to cause the plurality of mating surfaces to move toward each other; wherein the locking device is made of a bio-resorbable material (Col. 2, lines 24-31).

Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al in view of Nash et al and Goble et al to include the suture locking mechanism as taught by Goble et al. It would have been obvious to have applied any of the various suture locking mechanisms or device as taught by Goble et al instead of that disclosed by Evans in

Art Unit: 3773

view of Nash et al and Goble et al, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's in view of Nash et al and Goble et al. The motivation/suggestion for having the locking device to be made of a bio-resorbable material would have been to have the body to degrade the material without performing another surgery to remove the device.

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681), Goble et al (US Pat. No.: 5,702,397) and Schwartz et al (US Pat. No.: 6,293,961), as applied to claim 50 above, and further in view of Bonutti et al (US Pat. No.: 6,159,234).

In regard to Claim 53, Evans et al in view of Nash et al, Goble et al, and Schwartz et al discloses all the limitations of the claims but fails to disclose that the expansion of the collagen provides a force that tends to seat the at least one mating surface and the at least one lower surface. However, Bonutti et al discloses a suture locking mechanism that locks a suture by a force that tends to seat the at least one mating surface and the at least one lower surface (Fig. 20). By modifying vascular closure assembly of Evans et al in view of Nash et al, Goble et al, and Schwartz et al to include the suture locking mechanism of Bonutti et al, the collagen of Evan et al would be able to provide a force that tends to seat the at least one mating surface and the at least one lower surface. Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al in view of Nash et al, Goble et al, and Schwartz et al to include the suture locking mechanism as taught by Bonutti et al. It would have been obvious to have applied any

of the various suture locking mechanisms or device as taught by Bonutti et al instead of that disclosed by Evans, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's.

Response to Arguments

13. Applicant's arguments with respect to claims 1-62 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036.

The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773